

## US regulators to discuss 'female Viagra'

## June 4 2015

A drug nicknamed the "female Viagra" because it could help increase women's sex drive, will be discussed for a third time at a meeting of an advisory committee to US regulators Thursday.

If the US Food and Drug Administration gives flibanserin the go-ahead, it would be the first drug on the market to boost female libido.

But two attempts at bringing the drug to market have already failed in 2010 and 2013, given what experts described as inconclusive advantages when compared to a placebo.

Flibanserin, which is aimed at pre-menopausal <u>women</u>, also can have significant side effects including nausea, dizziness and sleepiness.

On Thursday, a committee of advisors to the FDA will hear more evidence from clinical studies and from experts both for and against the drug.

It will vote at the end of the day on whether or not the FDA should approve the drug, a decision that is non-binding but is usually followed by the regulatory agency.

After it was initially rejected by the FDA, flibanserin was sold by its developer, the German laboratory Boehringer Ingelheim, to a US firm called Sprout Pharmaceuticals.

For this latest attempt at approval, Sprout Pharmaceuticals is presenting



research that shows the medication does not affect women's ability to drive.

According to documents on the FDA website that describe a previous study of the drug, women taking flibanserin reported on average 4.4 sexually satisfying encounters per month, compared to 3.7 in a placebo group and 2.7 before beginning the study.

The difference between flibanserin and a sugar pill was deemed statistically insignificant in 2010 after a debate among the committee members which included seven women and four men.

The aphrodisiac properties of flibanserin were discovered accidentally when it was tested as an anti-depressant, the drug-maker says. Viagra's ability to cause an erection was discovered after it was tested as a heart medication. Other big drug companies have already thrown in the towel when it comes to developing a female Viagra, including Pfizer and Procter and Gamble.

Other experts have said the <u>drug</u> cannot possibly resolve the emotional complexities that make up female sexual desire.

Research has shown that at least 40 percent of women suffer to some extent from low sex drive.

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